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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,341	06/09/2006	Sung Youb Jung	430156.401USPC	7156

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EXAMINER	
DAHLE, CHUN WU	

ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/535,341	JUNG ET AL.	
	Examiner	Art Unit	
	CHUN DAHLE	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *8-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment to the claims, filed on December 10, 2008, is acknowledged.

Claims 1, 6, and 7 have been amended.
Claims 1-13 are pending.

Claims 8-12 stand withdrawn from further consideration by the Examiner, under 37 C.F.R. 1.142(b), as being drawn to nonelected invention.

Claims 1-7 and 13 are currently under consideration as they read on the elected invention of an Fc fragment and SEQ ID NO:8.

2. This Office Action will be in response to applicant's arguments, filed on December 10, 2008.

The rejections of record can be found in the previous Office Action, mailed on June 10, 2008.

3. Applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d) based on application REPUBLIC OF KOREA 10-2003-0080299, is acknowledged (See Application Data Sheet mailed on May 18, 2005). Copy of the certified copy of the priority document, REPUBLIC OF KOREA 10-2003-0080299, has been received.

4. In light of applicant's amendment to the claims, the prior objection to claim 6 has been withdrawn.

5. In view of applicant's amendment to the claims, the prior rejections under 35 USC 102(b) based upon Cox et al. (WO 01/03737, reference on PTO 892 mailed on November 15, 2007), Nakamura et al. (EP0227110), and Jendeberg et al. (J. Immunol. Method. 1997. 201:25-34 have been withdrawn.

6. In view of applicant's amendment to the claims, the following **New Grounds of Rejections** have been set forth herein.

7. This is a **New Ground of Rejection**. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 2, 7, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Maddon et al. (US Patent 6,034,223).

Maddon et al. teach a human Fc region from IgG, e.g. IgG2, chemically linked to non-peptide toxins (such as calicheamicin) via site-specific linkage through the N-linked sugar residues present on the Fc region (e.g. see column 7-8). Maddon et al. further teach pharmaceutical composition comprising said Fc region (e.g. see column 17 and claims 1-8).

It is noted that the claimed limitation of Fc "as a drug carrier" is considered intended use of the Fc fragment. The claim Fc is not limited by claim language of "as a drug carrier" since it does not limit the claims to a particular structure. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. See MPEP 2111.04.

Therefore, the reference teachings anticipate the claimed invention.

9. This is a **New Ground of Rejection**. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1-7 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maddon et al. (US Patent 6,034,223) in view of Presta (US Patent 6,737,056).

The teachings of Maddon et al. have been discussed, supra. Maddon et al. further teach that immunoconjugates comprising Fc region have a much longer half-life in vivo (e.g. see column 5). Furthermore, Maddon et al. teach that the effector functions associated with the Fc region can be disadvantage and the Fc region from human IgG2 does not bind Fc gamma receptors and thus is ideal for making immunoconjugates based upon IgG2 Fc (e.g. see column 6).

The reference teachings differ from the claimed invention by not describing aglycosylated IgG4 Fc fragment.

Presta teaches human IgG4 Fc region with reduced effector function (e.g. see columns 10). Presta further teaches host cells for making polypeptide including *E. coli.* Given that the instant SEQ ID NO:8 is the amino acid sequence of Fc region of IgG4, the prior art teachings of IgG4 Fc region would read onto claim 7 encompassing SEQ ID NO:8. Further, given that it was well-known in the art *E. coli.* host cells lack glycosylation enzymes for modifying human proteins, the prior art Fc made in *E. coli.* host cells would be aglycosylated.

It would thus be obvious to one of skill in the art at the time of the invention to substitute the human IgG2 Fc region that does not bind Fcγs and have less effector function taught by Maddon et al. with the aglycosylated human IgG4 Fc region taught by Presta since human IgG4 Fc region can be engineered to have reduce binding to Fcγs and decreased effector function. The substitution would have yielded predictable results of an aglycosylated human IgG4 Fc region that is covalently lined to a drug via non-peptide linker.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1-7 and 13 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of copending USSN 10/535,231 and claims 1-19 and 27-44 of copending USSN 10/535,232 for reasons of record.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Given that no terminal disclaimer signed by the assignee and fully complied with 37 CFR 3.73(b) was filed, the provisional rejection on the ground of nonstatutory obviousness-type double patenting is maintained.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Dahle whose telephone number is 571-272-8142. The examiner can normally be reached on 8:30-5:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Eileen O'Hara can be reached 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Chun Dahle
Patent Examiner

/Maher M. Haddad/

Primary Examiner,

Art Unit 1644